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National Aeronautics and Space Administration Office of Biological and Physical Research Washington, DC 20546-0001

Research Announcement

Research Opportunities for Flight Experiments in Space Life Sciences and Space Sciences

Notices of Intent Due: June 28, 2001 Proposals Due: August 28, 2001

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NASA Research Announcement

Research Opportunities
For Flight Experiments in
Space Life Sciences
and Space Sciences

This National Aeronautics and Space Administration (NASA) Research Announcement (NRA) solicits proposals for new research in selected areas of Fundamental Space Biology (FSB), Biomedical Research and Countermeasures (BR&C), Human Factors, and Astrobiology. This Announcement solicits research proposals that support the opening of the space frontier by exploring, using, and enabling the development of space. The research supported by the Office of Biological and Physical Research (OBPR) will increase knowledge of nature's processes using the space environment, aid in the exploration of the Solar System, support the achievement of routine space travel, and enrich life on Earth through the use of space technology and the application of biomedical knowledge. This research supports NASA's mission and the Office of Biological and Physical Research Strategic Plan. The research supported by the Office of Space Science will increase knowledge in the field of astrobiology. NASA will support a limited number of innovative, competitive, and multidisciplinary research and technology development studies selected through this solicitation process.

All participants in this NRA are strongly encouraged to promote general scientific literacy and public understanding of life sciences, the space environment, and the Office of Biological and Physical Research and Office of Space Science programs through formal and informal education opportunities. Where appropriate, supported investigators will be required to produce, in collaboration with NASA, a plan for communicating their work to the public.

Proposals for research already being funded as flight investigations will be of lower priority. Therefore, investigators are strongly encouraged to review the research currently funded by this office. Descriptions of the program tasks may be found at:

http://peer1.idi.usra.edu/peer review/taskbook/taskbook.html

Details relevant to the Flight Experiments in Space Life Sciences and Space Sciences program are included in the attached appendices and the associated document, *Space Life Sciences and Space Sciences Flight Experiments Information Package*, available at:

http://peer1.idi.usra.edu/peer_review/nra/01_OBPR_03.html

However, proposal submission criteria and evaluation criteria in this NRA supersede those in the companion documents.

This NRA is organized such that

- Appendix A provides a detailed description of the research areas solicited by this Announcement.
- Appendix B contains specific instructions for this NRA and relevant application forms.
- Appendix C contains general instructions applicable to the preparation of proposals in response to NASA Research Announcements.
- Appendix D contains specific risks and questions from the NASA Critical Path Roadmap that are relevant to the research emphases described in Section III of Appendix A.
- The Space Life Sciences and Space Sciences Flight Experiments Information Package describes the capabilities of the Space Shuttle and the International Space Station to support research in the Life Sciences and Space Sciences as well as ground-based facilities available to investigators, and procedures for their use.

Proposals submitted in response to this Announcement must address the research emphases defined in this Announcement. Those that do not will not be fully evaluated by NASA and will be returned to the investigator. **Proposals for purely ground-based research will not be accepted or considered for this Announcement**. Other announcements calling for focused research or utilization of unique resources may be issued throughout the year. Unsolicited proposals received at other times during the year will be held until the next annual review period if the proposed research is relevant to the programs described in this Announcement. However, NASA reserves the right to act in the best interest of the federal government in the matter of proposal acceptance and evaluation.

All proposals meeting the above criteria will be evaluated for scientific and technical merit by independent peer-review panels. The feasibility of carrying out the flight experiment will be evaluated by a panel of technical experts from NASA and other cooperating space agencies. Relevance to NASA's programmatic needs and goals will be evaluated separately by NASA. The government's obligation to make awards is contingent upon the availability of FY 2002 appropriated funds, which have not yet been approved by Congress. NASA does not provide separate funding for direct and indirect costs; thus, the amount of the award requested is the total of all costs submitted in the proposed budget. It is anticipated that a typical award will average \$200,000 (total annual cost). It is planned for selections to be announced by December 2001 and grants or contracts awarded shortly thereafter.

Proposals will be funded in one-year increments until the experiment is completed. However, flight experiments will be reviewed periodically for technical progress, availability of flight opportunities, implementation feasibility and to ensure that the science continues to be relevant. This review may result in a decision to deselect a flight experiment prior to its implementation or completion.

Participation in this Announcement is open to all categories of organizations, industry, educational institutions, other nonprofit organizations, NASA laboratories, and other government agencies. This solicitation is being coordinated with solicitations from the Canadian Space

Agency, the National Space Development Agency of Japan, the National Space Agency of Ukraine, and the European Space Agency. Proposals from entities within countries represented by these agencies should be made to the solicitation from the corresponding agency. Information on locating these solicitations may be found in the *Space Life Sciences Flight Experiments Information Package*. Under certain circumstances, NASA will review proposals from non-U.S. institutions, **but will not** fund non-U.S. institutions (see Appendix A, Section VII Announcement for details).

A notice of intent to propose is requested by June 28, 2001 (see Instructions, Appendix B of this Announcement). Notices of intent should be submitted via the World Wide Web (www) at:

http://peer1.idi.usra.edu/peer review/nra/01 OBPR 03.html

If you do not have access to the www, you may submit a notice of intent via email to:

noi@hq.nasa.gov

The subject heading of the e-mail message should read "Notice of Intent-01-OBPR-03." If you do not have access to e-mail, you may submit a notice of intent by U.S. Postal Service or commercial delivery to the address listed below for proposal submission.

Proposals must be submitted to NASA Peer Review Services by August 28, 2001. Proposals may not be submitted electronically. Proposals <u>must</u> be received by 4:30 PM Eastern Time. Proposals and notices of intent mailed through the U.S. Postal Service by express, first class, registered, or certified mail are to be sent to the following address:

NASA Peer Review Services SUBJECT: 01-OBPR-03 Flight Experiments in Space Life Sciences and Space Sciences 500 E Street, SW Suite 200 Washington, DC 20024

Proposals and notices of intent that are hand delivered or sent by commercial delivery or courier services are to be delivered to the above address between 8:00 AM and 4:30 PM. The telephone number, 202-479-9030, may be used when required for reference by delivery services. NASA Peer Review Services (NPRS) cannot receive deliveries on Saturdays, Sundays, or federal holidays. Upon receiving a proposal, NPRS will send notification to the investigator confirming its arrival; however, there will not be a response from the Space Life Sciences and Space Sciences Program office.

In order to be accepted as a complete submission, proposals **must include** completed copies of the appropriate forms provided in Appendix B.

The following items apply only to this Announcement:

Solicitation Announcement Identifier: NRA 01-OBPR-03 Number of Copies Required: Original + 25 copies

Notices of Intent Due:

Proposals Due:

Selection Announcement:

Funding Begins:

June 28, 2001

August 28, 2001

December 2001

1st Quarter 2002

Selecting Officials:

For Flight Experiments in Fundamental	Director
Space Biology	Fundamental Space Biology Division
	Office of Biological and Physical Research
For Flight Experiments in Biomedical	Director
Research and Advanced Human Support	Bioastronautics Research Division
Technology	Office of Biological and Physical Research
For Flight Experiments in Astrobiology	Director
	Research Program Management Division
	Office of Space Sciences

Additional information is available from:

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ISS and Shuttle Hardware and Mission	Peter Ahlf
Constraints for Biomedical Research and	NASA Headquarters, Mail Code UB
Countermeasures and Human Factors	Washington, DC 20546-0001
	Telephone: (202) 358-2530
	Fax: (202) 358-4168
	E-mail: pahlf@hq.nasa.gov

This Announcement is restricted to the programs named above and described in detail in Appendix A. Potential investigators should read with care the program descriptions that are of interest and focus their proposals on the specific research emphases defined in this Announcement.

Your interest and cooperation in participating in this effort is appreciated.

Original Signed by

Kathie L. Olsen, Ph.D. Acting Associate Administrator Office of Biological and Physical Research

Flight Experiments in Space Life Sciences and Space Sciences

I. Description of the Opportunity

This Appendix defines the research program and elements encompassed by this Announcement, describes the specific areas of flight research that proposals should address, and describes the specific emphases that are acceptable for submission in response to this Announcement. **Proposals for purely ground-based research will not be accepted or considered for this Announcement**. It is important that the prospective investigator read the relevant section(s) carefully, as many of the programmatic emphases are different from those appearing in previous Division Announcements. In addition, this Appendix includes guidelines for preparing and submitting proposals and defines the administrative policies governing the program and investigators.

II. Fundamental Space Biology and Astrobiology Research Emphases

The major scientific objective of Fundamental Space Biology is to expand our understanding of fundamental biological processes and the mechanisms by which these processes sense, respond, adapt, and evolve in the space environment. Objectives are accomplished using a spectrum of gravitational conditions or model systems (e.g., hypergravity, simulated hypogravity, microgravity, and other appropriate models of gravity effects) as research tools or by determining the effects of the interaction of gravity (hypergravity or microgravity) with other space environmental factors (e.g., radiation) on biological systems. The emphasis is on using these gravitational research tools to advance fundamental knowledge in the biological sciences. Research that applies this knowledge to NASA's other goals of enabling human exploration of space and improving the quality of life on Earth is also encouraged.

Experiments requiring up to 120 days exposure to the space environment are being solicited. Proposals must comply with the operational and hardware constraints and requirements associated with the current space flight program. Investigators of flight experiments should consult the *Space Life Sciences and Space Sciences Flight Experiments Information Package* for this information. Also, please see Section IV of this Appendix, Flight Experiment Opportunities and Constraints, for additional information. Note that assurance of compliance with applicable federal regulations regarding human subjects or animal care and use is required as part of the proposal submission process (see the "Special Matters" instructions in Appendix B).

A. Research Emphases for Fundamental Space Biology

The Fundamental Space Biology Division is interested in basic research that addresses the effects of the space environment on animal and plant systems across a range of model organisms. This solicitation is only for flight experiments using animal and plant cell cultures, simple organisms (i.e., E. coli, S. cerevisiae, C. elegans, D. melanogaster, and A. thaliana) and avian eggs (for developmental studies). Research using rodents is not being solicited in this Announcement. Investigators should consult the Space Life Sciences and Space Sciences Flight Experiments Information Package for information about specimen types that will be accommodated through this solicitation. Research related to biological systems known or believed to be influenced by gravitational force (e.g., bone, muscle, endocrine system, neurological and vestibular systems) or by other aspects of the space environment will be emphasized. In coordination with one of the Biomedical Research and Countermeasure Program's primary research thrusts (see section III A. of this appendix), proposals related to musculoskeletal research are highly encouraged. It should be noted that in order to achieve program balance, specific topics that are currently well represented in our portfolio will be de-emphasized. Investigators are encouraged to review summaries of the research currently funded in this Program by accessing the Life Sciences Program Tasks and Bibliography (Life Sciences Task Book) at:

http://peer1.idi.usra.edu/peer review/taskbook/taskbook.html

1. <u>Molecular Structures and Physical Interactions</u>

This element emphasizes physical effects of the space flight environment on cells and organisms. These physical effects may include static boundary layer effects on gas exchange, changes in heat transfer, lack of convective fluid movements, and alterations in diffusion-limited metabolic processes. This element seeks to determine how these factors affect the growth, development, and function of single-celled and multicellular organisms.

2. Developmental Biology

NASA's goals in developmental biology are to determine the role of gravity in normal development and function, how gravity and other aspects of the space environment may affect the capacity of organisms to reproduce, and the mechanisms by which subsequent generations are affected. Research in this area should focus on elucidating the influence of gravity during critical periods of development, including neural and vestibular development. Also, the effect of the space environment on behavior, reproduction, life span, senescence, and subsequent generations is of interest. Examples of important issues concerning developmental biology in space are whether: 1) normal development depends on gravity exposure during critical periods of development, especially for the vestibular and motor systems and the multiple sensory systems that interact with them; 2) exposure to the microgravity environment results in irreversible changes

in morphology and function in adulthood; and 3) an organism can undergo a complete life cycle or several life cycles in the microgravity environment.

3. <u>Cellular and Molecular Biology</u>

The principal aim of this element is to support research at the genetic, molecular, and cellular levels to elucidate specific cellular phenomena that are affected by conditions of microgravity and to develop an understanding of the molecular mechanisms by which these changes are induced. Research in this area should address how basic cellular function and properties (e.g., mechanoreception, signal transduction, gene regulation and expression, integrin function and structure, cytoskeletal structure and function, etc.) may be directly or indirectly impacted by altered gravitational force and other space related effects. Of particular interest is how the space environment may affect cellular processes such as regulation of the cell cycle, apoptosis, cell senescence, and cell growth. Cellular and molecular studies that begin to suggest countermeasure strategies for the physiological changes seen in whole animals in response to the space environment are also highly encouraged.

4. <u>Organismal and Comparative Biology</u>

The organismal element seeks to use the comparative approach to understand how whole organisms transduce, perceive, integrate, and respond to a gravitational force; the effect of hypergravity and hypogravity on developmental, regenerative, and reproductive processes; the regulation of physiological systems (e.g., the nervous system); and how gravity and other environmental factors interact. The comparative element elucidates the physiological, cellular, and molecular mechanisms of the effects of gravity and space flight on the growth, development, composition, and physiological and behavioral functions of animals and plants across the phylogenetic scale.

5. Gravitational Ecology

This element invites proposals directed at understanding how gravity might affect the structure, function, and possibly the evolution or stability of ecosystems, particularly as they might relate to spacecraft or planetary habitats. By conducting ecological research at different gravity levels and in the unique spacecraft environment, it will be possible to determine the influence of those factors on the function of ecosystems and their interaction with the characteristics of life support system environments for human crews. Examples of such research might include studies of chemical or pathogen species released by one organism that may have important characteristics that impact other organisms.

B. Research Emphasis for Astrobiology

The goals and objectives of the Astrobiology Program are available through the

Astrobiology Web page (http://astrobiology.arc.nasa.gov/roadmap/index.html). Proposals for research on the International Space Station that address any of these goals are solicited. It is thought that several objectives in Astrobiology can be accomplished in the space environment including areas ranging from prebiotic chemistry to some aspects of life in extreme environments. Note that proposals are not solicited that address the space environment itself but only those that use the unique features of the space environment as a tool to address the goals and objectives of the Astrobiology Program.

NOTE: Astrobiology proposals that also address aspects of fundamental biology solicited in this Announcement may be funded by OBPR. Such proposals would address goal #10 of the NASA Astrobiology Roadmap, "Understand the Response of Terrestrial Life to Conditions in Space or on Other Planets." For other proposals, in order to be eligible for funding from the Office of Space Sciences, two proposals must be submitted: one proposal to this solicitation, and a second proposal to the Office of Space Sciences "Announcement of Opportunity for the Explorer Program: Medium Class Explorers and Missions of Opportunity" (the "MIDEX AO"). A successful proposal will acquire the flight opportunity through this competition and funding through the MIDEX competition. Information on the MIDEX AO can be found at the Space Science Web page under research opportunities (http://spacescience.nasa.gov/).

III. Biomedical Research and Countermeasures and Human Factors Research Emphases

This solicitation requests flight research proposals that will lead to the development of effective countermeasures or operational techniques for problems associated with one of three research areas: (1) bone and muscle loss; (2) human factors and behavior and performance; and (3) clinical capability. The first two research areas represent the primary thrusts of this solicitation while the third is included as a supplemental area utilizing available resources not targeted to the primary areas. In the primary thrust areas, a selected investigator will become a member of a research team pursuing an integrated set of related objectives. While an invitation to participate on a team will be based on the strengths of an individual proposal, successful applicants will be required to work with other team members to develop an integrated set of objectives that can be met within fiscal and flight resource constraints. Development of this integrated approach may result in modification, transfer, or deletion of some objectives put forth in an individual proposal. A majority of the ISS resources (crew time, launch and return logistics, etc.) available for NASA biomedical research during the target timeframe for implementation of experiments selected from this NRA will be provided to these three groups to carry out an integrated set of objectives. In the supplemental area of Clinical Capability, selected studies may be either team or individual investigator based.

Proposals must clearly and directly benefit the health and/or performance of astronauts during or after space flight, and should also benefit people on Earth. Benefits of the proposed research may take any of the following forms:

• risk assessment, reduction and/or acceptability (monitoring and/or modeling);

- scientific knowledge related to the development of appropriate countermeasures or operational procedures (mechanisms and/or processes);
- development of risk mitigating requirements (pharmacological, nutritional/dietary, exercise regimes and fitness levels, rehabilitation, and/or stress reduction strategies);
- development of procedures for medical intervention (diagnosis and treatment, and/or post-landing rehabilitation);
- development of improved procedures for crew screening and enhancing crew selection criteria (physiological, genetic and psychological criteria, applicable to the individual and/or the group);
- improvement of crew training procedures (pre-, in- and postflight, including the use of expert systems);
- enhancement of design specifications (related to environmental habitability, including lighting and noise levels, hygiene, food systems, etc., and the use of artificial gravity and/or mechanical assistance devices) and improvement of mission operations (monitoring of physiological, behavioral and environmental aspects); and
- technology development which will aid in carrying out the research objectives of this solicitation.

NASA and the National Space Biomedical Research Institute have developed a Critical Path Roadmap to help guide its bioastronautics research in systematically reducing or eliminating the risks to astronaut health, safety, and performance during and after space flight. Of the 55 risks identified in the Critical Path Roadmap (CPR), this solicitation focuses on the 11 risks associated with altered musculoskeletal function and three of the risks associated with human behavior and performance. The CPR poses 250 unique critical questions whose answers are considered essential to mitigate the 55 risks. To be responsive, proposals submitted in response to this solicitation MUST explicitly seek to answer one or more of the critical questions related to musculoskeletal function, human factors, or behavior and performance. A list of the CPR risks and the associated critical questions is provided in Appendix D. Further details can be obtained from the CPR Web site (http://criticalpath.jsc.nasa.gov/).

A. Primary Research Thrust: Bone and Muscle Loss

One primary research emphasis of this solicitation is to develop or improve preflight or inflight countermeasures and postflight rehabilitation techniques that protect the health, safety, and performance of humans in space from deterioration in musculoskeletal function. Research proposals that are highly likely to lead to verifiable countermeasures within three to five years are solicited. Excellent proposals will include a plan to account for interactions among diet, exercise, pharmacologic or other potential countermeasures for maintaining musculoskeletal function and performance; such proposals will also assess the impact of musculoskeletal countermeasures on other physiological systems.

Of particular interest are research proposals that:

- use accessible, functional measurements of endpoints (e.g., bone density, muscle size, and strength);
- test appropriate pharmacological or hormonal replacement countermeasures,

including anti-resorptive bone agents, growth hormone, and/or sex hormone replacement therapy; (Note: the use of drugs requires convincing data that they can be safely administered in the space flight environment.)

- account for nutritional requirements and dietary factors;
- provide evidence that other indices of muscle function (e.g., surface electromyography) correlate to the forces generated by specific muscle groups during exercise;
- study the use of resistance exercise hardware to prevent loss in muscle strength and mass. Such research could compare the effectiveness of different exercise prescriptions (e.g., through crew exercise time, intensity, duration, frequency, etc.) or could assess the amount of work that is actually being performed. In the event that design, performance, and instrumentation requirements for resistance exercise hardware exceed those of the available hardware (the "Interim Resistive Exercise Device" which is described in the Flight Experiment Information Package), the requirements should be clearly specified so that NASA could consider the development of a new device to support highly meritorious proposals.
- include studies that can lead to new rehabilitation strategies for enhancing and monitoring the recovery of the musculoskeletal system following space flight.

B. Primary Research Thrust: Human Factors and Behavior & Performance

A second primary research emphasis is to develop or improve preflight or inflight countermeasures or postflight rehabilitation techniques that will result in measurable improvement in the areas of human factors, psychosocial adaptation, human system design, and human performance optimization. Research proposals that are highly likely to lead to verifiable countermeasures within three to five years are solicited. Excellent proposals will include a plan to account for the impact of the proposed countermeasures on the whole human subject.

Human factors proposals are solicited which:

- assess and predict crew performance and efficiency;
- evaluate effects of the crew-system interfaces on crew performance;
- develop and validate non-intrusive methods of assessing human performance that can be related to crew efficiency and productivity.

Behavior and performance proposals are solicited which:

- are designed to understand changes in individual and team performance, and develop countermeasures to prevent or ameliorate detrimental effects;
- identify behaviors, experiences, personality traits and leadership styles that contribute to successful crew performance during long-duration space flight and develop and validate methods to identify these factors during the crew selection process;
- identify acute and long-term effects of exposure to the space environment (microgravity, isolation, stress) on:
 - human cognition, sensation, perception, learning, problem-solving, and decision making;

- the nervous system and related neurobehavioral mechanisms;
- human emotional reactivity, stress responses, mood modulation, and vulnerability to affective disorders.

C. Supplemental Research Objective: Clinical Capability

Research in the supplemental area of clinical capability will utilize spacecraft resources (e.g., crew time, launch and return logistics) not required for the primary research thrusts. In most cases, studies in this area will be implemented as individual investigator experiments, although teaming of investigations may be requested in some cases. Successful proposals will focus on the development of medical knowledge and technologies required to maintain human health and performance in space and on return to Earth. Clinical research proposals to develop tools to deal with acute medical scenarios in space are encouraged (e.g., musculoskeletal injuries including sprains, contusions and fractures; wounds, lacerations, and burns; toxic exposures and acute anaphylaxis including drug reactions). In addition, this area includes research required to address and answer specific questions about inflight on-orbit management of acute medical problems.

The highest priority proposals for clinical capability should address:

- development and validation of diagnostic and treatment technologies, protocols and procedures necessary to effectively diagnose, treat, and recover patients from likely acute medical scenarios in space;
- the most effective options, protocols and technologies to support patient transport and return to Earth for definitive medical care;
- mechanisms and changes that occur during space flight or immediately postflight in the therapeutic effectiveness of representative classes of medications;
- the effects and implications of space-flight alterations in human physiology on the absorption, distribution, metabolism, clearance, excretion, clinical efficacy, side effects and drug interactions for clinically useful medications. The most important classes of drugs are antibiotics and anti-infective agents, CNS medications, such as anti-nausea and sleep, that may affect performance and cognitive acuity, and medications with narrow therapeutic windows such as cardiovascular agents (e.g., anti-arrhythmic). NOTE: During this phase of the International Space Station it is not expected that it will be possible to conduct standard timed urine and blood sampling, therefore the proposal of alternative methodologies is encouraged.
- the most appropriate dosage forms and routes of administration for the most commonly administered and clinically useful medications administered in space flight; and
- diagnostic and laboratory technologies necessary to manage medication side effects and toxicity during space flight.

D. Countermeasure Evaluation and Validation Project

Potential investigators should be aware that NASA has established a separate solicitation and review process for the final evaluation and validation step for specific

countermeasures prior to their implementation as part of regular medical operations in space. No solicitations have been issued for this program at this time, but one is planned for release later in 2001. Any proposals submitted in response to the present solicitation which appear to focus on the final evaluation and validation of a specific countermeasure may be held and evaluated later through the review process established for the Countermeasure Evaluation and Validation Program. Access to the future solicitation for this program can be found by following the "research opportunities" link at the following Web address: http://spaceresearch.nasa.gov.

IV. Flight Experiment Opportunities and Constraints

Two types of flight experiments are currently solicited: (1) pre-mission and post-mission studies involving data collection and analysis of biological specimens prior to and on return from space, and (2) on-orbit experiments that can be implemented on the space platforms of the Space Shuttle or the ISS. Proposals must be compatible with the operational constraints and capabilities of the International Space Station and the Space Shuttle. The *Space Life Sciences and Space Sciences Flight Experiments Information Package* provides detailed information on these constraints as well as a description of the unique aspects of the evaluation and selection process for flight experiments.

All flight experiments must address one or more of the research program emphases defined in Sections II and III above. Flight investigations must represent mature studies strongly anchored in previous ground-based research or previous flight research. Ground-based research may, and usually must, represent one component of a flight experiment proposal. However, that research should be limited to activities that are essential to the final development of an experiment for flight and for the completion and publication of the scientific results of the experiment. Preparatory ground research designed to define a mature space flight experiment should be proposed separately and in its own right as part of the ground-based program.

Opportunities for flight experiments continue to be extremely limited at this time. For the next five years, a majority of the capacity of the Space Shuttle fleet is dedicated to assembly and operation of the ISS. Therefore, opportunities for Shuttle-based experiments are limited. It will be possible to conduct experiments onboard the ISS. However, ISS experiments will be severely constrained by limitations on resources such as mass, volume, power, re-supply of consumables, and crew time. Priority for initial use of some research hardware on the ISS will be for validation testing of the hardware operation and capabilities. Detailed limitations on Space Shuttle and ISS flight experiments are included in the *Space Life Sciences and Space Sciences Flight Experiments Information Package*. Proposals requiring resources beyond the capabilities defined in this document should <u>not</u> be submitted in response to this Announcement.

Flight experiments that are selected as a result of this Announcement will enter a definition phase. The experiment will not be considered for an actual flight prior to successful completion of the definition phase. Selection of a flight experiment through this Announcement does not represent a guarantee for flight.

V. Proposal Evaluation and Awards Selection Process

The following information is specific to this NRA and **supersedes** the information contained in Sections I and J of Appendix C, *Instructions for Responding to NASA Research Announcements*. In addition, proposal submission criteria and evaluation criteria in the NRA supersede those in the companion documents.

All proposals must comply with the general requirements of this Announcement as described in both Appendices B and C. Appendix B contains specific requirements and explanations that apply to this Announcement. Appendix C outlines the NASA-specified requirements for proposal submission and should be used for clarification and reference. Upon receipt, proposals will be reviewed for compliance with the requirements of this Announcement. This includes:

- 1. Submission of complete proposals specified in this Announcement. Proposals must be responsive to the areas of program element emphasis described in this Announcement and include a project description that is not more than 20 pages in length.
- 2. Submission of appropriate Institutional Review Board (IRB) or Animal Care and Use Committee (ACUC) certification for all proposals using human or animal test subjects.
- 3. Submission of a budget that is within the guidelines specified in this Announcement and is for a funding period not exceeding three years in duration.
- 4. Proposals that are revised versions of proposals previously submitted to NASA must be clearly designated as such on the proposal cover page (Form A) and must contain an explanation of how the revised proposal has addressed criticisms from previous NASA review. This explanation should be presented in a separate section of **no more that two pages at the beginning of the project description** and is in addition to the 20 pages allowed for the project description. Related changes to the research plan should be highlighted in the body of the project description.
- 5. Submission of all other appropriate forms as required by this NASA Research Announcement (refer to Appendix B).

Note: At NASA's discretion, non-compliant proposals may be withdrawn from the review process and returned to the investigator without further review.

Compliant proposals submitted in response to this Announcement will undergo the following review process.

A merit review will be conducted for all proposals. Only those proposals most highly rated in the merit review process will undergo the following additional reviews:

- Flight feasibility (where applicable)
- Relevance / cost: Relevance to NASA Programs and proposed project cost

Although the most important factor in evaluation is the merit review, in order to be selected, proposals must also be feasible for flight and meet relevant cost criteria.

A. Intrinsic Scientific or Technological Merit Review

The **first review** will be a merit review by a panel of scientific or technology experts. The number and diversity of experts required will be determined by the response to this research announcement and by the variety of disciplines represented in the proposals relevant to the research emphases described in Section II of this Appendix. The merit review panel will assign *a score from 0-100* or a designation of "not recommended for further consideration" based upon the intrinsic scientific or technological merit of the proposal.

The score assigned by this panel will not be affected by the cost of the proposed work nor will it reflect the programmatic relevance of the proposed work. However, the panel will have the opportunity to include in their critique of each proposal any comments they may have concerning the proposal's budget and relevance.

All of the following will be used in determining the merit score:

- **Significance:** Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge or technology be advanced? What will be the effect of these studies on the concepts, methods, or products that drive this field? Is there a significant societal or economic impact?
- **Approach:** Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Is the proposed approach likely to yield the desired results? Does the applicant acknowledge potential problem areas and consider alternative tactics?
- Innovation: Does the project employ appropriate novel concepts, approaches, or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?
- **Investigator:** Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and any co-investigators? Is the evidence of the investigator's productivity satisfactory?
- **Environment:** Does the scientific environment in which the work will be performed contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

B. Flight Feasibility Review

A **second review** will be an evaluation of the flight feasibility of the proposed work on a space platform. This review is described in the *Space Life Sciences and Space Sciences Flight Experiments Information Package*.

C. Evaluation of Programmatic Relevance and Cost

The **third review** will evaluate the programmatic relevance and cost of all proposed work. This review will be conducted by NASA program scientists and managers. Evaluation of the cost of a proposed effort includes consideration of the realism and reasonableness of the proposed cost and the relationship of the proposed cost to available funds. Programmatic relevance will include an evaluation of how the proposed work may help achieve an appropriate balance of scientific and technical tasks required by critical research issues faced by the NASA programs.

D. Development of Selection Recommendation

The information resulting from these three levels of review, as described above, will be used to prepare a **selection recommendation** developed by NASA program scientists and managers for each of the program elements described in this Announcement. This recommendation will be based on:

- 1. The scientific or technological merit review score from the peer review panel
- 2. The results of the flight feasibility review
- 3. The programmatic relevance and cost of each proposal.

This **selection recommendation** is the responsibility of the NASA program scientist(s). Selection for funding will be made by the Director of the Fundamental Space Biology Division for experiments related to the Fundamental Space Biology Program, by the Director of the Bioastronautics Research Division for experiments related to the Biomedical Research and Countermeasures Program and the Advanced Human Support Technology Program, and by the Director of the Research Program Management Division for experiments related to the OSS Astrobiology Program.

VI. Eligibility

All categories of U.S. institutions are eligible to submit proposals in response to this NRA. Principal Investigators may collaborate with universities, Federal Government laboratories, the private sector, and state and local government laboratories. In all such arrangements, the applying entity is expected to be responsible for administering the project according to the management approach presented in the proposal.

The applying entity must have in place a documented base of ongoing high quality research in science and technology or in those areas of science and engineering clearly relevant to the specific programmatic objectives and research emphases indicated in this Announcement. Present or prior support by NASA of research or training in any institution or for any investigator is not a prerequisite to submission of a proposal or a competing factor in the selection process.

All types of institutions are eligible to submit proposals in response to this NRA, but only approved proposals from U.S. institutions will be selected for funding.

VII. Foreign Proposals

Flight experiment proposals may be from US or international entities according to the following rules. This solicitation is coordinated with solicitations from the European Space Agency (ESA), Canadian Space Agency, National Space Development Agency of Japan, and The National Space Agency of Ukraine. Flight experiment proposals that have principal investigators from entities of Canada, Japan, Ukraine, or the member countries of ESA must be submitted to their respective agency, including those with U.S. researchers and co-investigators. Proposals for flight experiments with principal investigators from entities of countries other than the U.S., Canada, Japan, Ukraine, or the member countries of ESA will not be reviewed unless they involve substantive co-investigator collaboration from one of the above-mentioned countries. Proposals for flight experiments with principal investigators from entities of countries other than the U.S., Canada, Japan, Ukraine, or the member countries of ESA, and with substantive co-investigator collaboration from one of the above-mentioned countries should be submitted to the solicitation of the respective space agency associated with the country in which the co-investigator's entity is located. U.S. co-investigators who are collaborating on such proposals must ensure that their scientific role is clearly delineated in the proposal, that their expertise is shown to make a substantial contribution, and that their funding requirements are included in the proposal.

Foreign entities are not eligible for funding from NASA. Therefore, if the proposal involves substantial collaboration with a U.S. institution, a cost plan for only the participation of the U.S. entity must be included. Proposals from U.S. entities that include foreign participation must be endorsed by the respective government agency or funding/sponsoring institution in the country from which the foreign entity is proposing. Such endorsement should indicate that the proposal merits careful consideration by NASA, and if the proposal is selected, sufficient funds will be made available to undertake the activity as proposed.

All foreign proposals must be typewritten in English and comply with all other submission requirements stated in the NRA. All proposals will undergo the same evaluation and selection process as those originating in the U.S.

All proposals must be received before the established closing date. Foreign sponsors may, in exceptional situations, forward a proposal without endorsement if the endorsement is not possible before the announced closing date. In such cases, the NASA sponsoring office should be advised when a decision on endorsement can be expected.

Successful and unsuccessful foreign entities will be contacted directly by the NASA sponsoring office. Copies of these letters will be sent to the foreign sponsor. Should a U.S. proposal with foreign participation be selected, NASA's Office of External Relations will arrange with the foreign sponsor for the proposed participation on a no-exchange-of-funds basis, in which NASA and the foreign sponsor will each bear the cost of discharging their respective responsibilities.

Depending on the nature and extent of the proposed cooperation, these arrangements may entail:

- (i) An exchange of letters between NASA and the foreign sponsor; or
- (ii) A formal Agency-to-Agency Memorandum of Understanding (MOU).

Export Control Guidelines Applicable to Foreign Proposals and Proposals Including Foreign Participation. (1) Foreign proposals and proposals including foreign participation must include a section discussing compliance with U.S. export laws and regulations, e.g., 22 CFR Parts 120-130 and 15 CFR Parts 730-774, as applicable to the circumstances surrounding the particular foreign participation. The discussion must describe in detail the proposed foreign participation and is to include, but not be limited to, whether or not the foreign participation may require the prospective investigator to obtain the prior approval of the Department of State or the Department of Commerce via a technical assistance agreement or an export license, or whether a license exemption/exception may apply. If prior approvals via licenses are necessary, discuss whether the license has been applied for or if not, the projected timing of the application and any implications for the schedule. Information regarding U.S. export regulations is available at the following Web addresses: http://www.pmdtc.org and http://www.bxa.doc.gov. Investigators are advised that under U.S. law and regulations, spacecraft and their specifically designed, modified, or configured systems, components, and parts are generally considered "Defense Articles" on the United States Munitions List and subject to the provisions of the International Traffic in Arms Regulations (ITAR), 22 CFR Parts 120-130.

VIII. Program Reporting

It is expected that results from funded research will be submitted to peer-reviewed journals as the work progresses. Only published papers that acknowledge NASA's support and identify the grant or contract will be counted as resulting from the research project and used to evaluate its productivity.

Annual Reporting. Investigators will be expected to provide NASA with annual summary information. This information will consist primarily of:

- an abstract
- a bibliographic list
- copies of publications
- a statement of progress
- potential scientific, technological, economic or societal impact

This information will be made available to the scientific community and will be used to assess the strength of the Division's programs. It will also serve as the basis for determining the degree of progress of the project.

Annual Task Book Reporting. The Office of Biological and Physical Research publishes a comprehensive annual document titled Life Sciences Tasks and Bibliography (Life Sciences Task Book) which includes descriptions of all peer-reviewed activities funded by the division during the previous fiscal year. Since its inception in fiscal year 1995, the Task Book has served as an invaluable source of information for NASA Life Sciences as well as the scientific and technical communities

Investigators are required to provide information for this publication on an annual basis. Please note that this requirement is in addition to the annual report which investigators are required to submit at the end of each funding cycle. Supplying the requested information for the Life Sciences Task Book does NOT fulfill the requirement for the annual report. Unlike the annual report, information requested for the Task Book must be for the government's fiscal year rather than the project funding cycle and brief.

The information requested for inclusion in the Task Book consists primarily of:

- an abstract
- a brief statement of progress during the fiscal year
- a brief statement of benefits of the research with respect to life on Earth
- a bibliographic list for the fiscal year
- a copy or reprint of each publication listed in the bibliography for the fiscal year
- a listing of presentations or activities conducted at K-12 educational institutions
- a listing of interactions, presentations, or other activities with the general public

Note that although this publication will be made available to the general scientific community, it is not a substitute for traditional scientific reporting in journals and elsewhere.

Final Report. A final report is required that shall include all peer-reviewed publications.

Principal Investigator Meetings. In Fiscal Year 2003, and in alternating years thereafter, a Bioastronautics Investigators Workshop will be held. The meeting will be held in January in Houston, Texas. All Principal Investigators funded through the Biomedical Research and Countermeasures Program will be expected to attend and the cost of this travel should be reflected in the budget of the proposal.

IX. Bibliography

1. Acceptability of Risk From Radiation - Application to Human Space Flight. April 30, 1997. Symposium Proceedings No. 3. Bethesda, MD: National Council on Radiation Protection and Measurements.

- 2. **Astrobiology Roadmap**. Web address: http://astrobiology.ARC.NASA.gov/roadmap/index.html
- 3. A Strategy for Research in Space Biology and Medicine in the New Century. National Academy of Science. National Research Council Committee on Space Biology and Medicine. Mary J. Osborn, Committee Chairperson. 1998. Washington D.C: National Academy Press. Web address: http://www.nas.edu/ssb/csbm1.html
- 4. Cell & Molecular Biology Research in Space. *The FASEB Journal*, Vol. 13, Supplement, 1999.
- 5. **Center for Advanced Studies in the Space Life Sciences** contains a list of workshops and seminars sponsored by the Center. The proceedings and final reports of these workshops are also posted as they become available. Web address: http://www.mbl.edu/html/NASA/
- 6. **Countermeasure Evaluation and Validation Project**. Web address: http://spaceresearch.nasa.gov
- 7. Critical Path Roadmap. Web address: http://criticalpath.jsc.nasa.gov/
- 8. **Guidance on Radiation Received in Space Activities**. July 31, 1989. NCRP Report 98. Bethesda, MD: National Council on Radiation Protection and Measurements.
- 9. **Integrative Physiology in Space**. *European Journal of Physiology*, Volume 441, No. 2-3, Supplement, 2000.
- 10. **International Workshop on Bone Research in Space**. *Bone, Official Journal of the International Bone and Mineral Society*, Volume 22, Number 5 (Supplement), 1999.
- 11. **International Workshop on Cardiovascular Research in Space**. *Medicine and Science in Sports and Exercise*, Volume 28, Number 10 Supplement, S1-S112 1996.
- 12. **International Workshop on Human Factors in Space**. *Aviation, Space, and Environmental Medicine*, Volume 71, No. 9, Section II, Supplement, 2000.
- 13. **Life Sciences Program Tasks and Bibliography (Task Book)** for FY 1995 through FY 1999 are available online at the following Web address: http://peer1.idi.usra.edu/peer review/taskbook/taskbook.html
- 14. **Medical Policies and Requirements Document**. National Aeronautics and Space Administration, Medical Policy Board. Arnauld Nicogossian, Chairperson. NASA Headquarters. This document is currently in revision. Please contact Dr. Richard Williams (202-358-4410) for more information.

- 15. **Modeling Human Risk: Cell & Molecular Biology in Context**. June, 1997. Ernest Orlando Lawrence Berkeley National Laboratory Report LBNL-40278. Berkeley, CA.
- 16. **Muscle Research in Space: International Workshop**. *International Journal of Sports Medicine*, Volume 18, Supplement 4, S255-S334, 1997.
- 17. NASA Space Science Homepage. http://spacescience.nasa.gov
- 18. **NASA Strategic Program Plan for Space Radiation Research**. Web address: http://www.hq.nasa.gov/office/olmsa/lifesci/Strategic Plan.pdf
- 19. **Plant Biology in Space: Proceedings of the International Workshop**. *Planta*, Supplement to Volume 203, 1997.
- 20. Radiation Hazards to Crews of Interplanetary Missions: Biological Issues and Research Strategies. 1996. Washington, DC. Task Group on the Biological Effects of Space Radiation. Space Studies Board Commission on Physical Sciences, Mathematics and Applications, National Research Council. National Academy Press.
- 21. **Review of NASA's Biomedical Research Program**. Committee on Space Biology and Medicine, Space Studies Board, National Research Council. National Academy Press, 2000.
- 22. **Shielding Strategies for Human Space Exploration**. J. W. Wilson, J. Miller, A. Konradi and F. A. Cucinotta, Editors. NASA CP-3360, December 1997, pp. 456. Also available from the NASA Langley Technical Reports Web address: http://techreports.larc.nasa.gov/ltrs/ltrs.html
- 23. Space Life Sciences and Space Sciences Flight Experiments Information Package. Web address: http://peer1.idi.usra.edu/peer review/nra/01 OBPR 03.html
- 24. The Space Life Sciences Data Archive (LSDA) is an online database containing descriptions and results of completed NASA-sponsored flight experiments. Descriptions are included of experiments, missions, procedures, hardware, biospecimens collected, personnel, and documents. Biospecimens that are available for research purposes are described in detail. A limited number of experiments contain final reports and spreadsheet data suitable for downloading. Data from human subjects are unavailable online for reasons of privacy.

Web address: http://lsda.jsc.nasa.gov LSDA Help Desk: (281) 483-7876 Email: lsda@semail.jsc.nasa.gov

- 25. **Space Life Sciences Ground Facilities Information Package**. Web address: http://peer1.idi.usra.edu/peer_review/nra/ILSRA_2001
- 26. **SPACELINE**, an online bibliographic database, is available for searching for references

to publications about space life sciences research. A cooperative venture between NASA's Office of Biological and Physical Research and the National Library of Medicine (NLM), SPACELINE is similar in structure to NLM's MEDLINE database. Individuals can perform their own searches with the new web-based interface. Additional information may be obtained from the SPACELINE Office. Phone: 301-295-2482;

Email: SPACELINE@usuhs.mil Web address 1: http://spaceline.usuhs.mil

Web address 2: http://igm.nlm.nih.gov (MEDLINE)

- 27. **Space Neuroscience Research**. *Brain Research Reviews*, Volume 28, Numbers 1/2, Special Issue, 1998.
- 28. **Space Physiology and Medicine, 3rd ed**. A. Nicogossian, C. Huntoon, and S. Pool. (Eds.). 1994. Philadelphia, PA: Lea & Febiger.
- 29. **Task Force on Countermeasures**. This report incorporates the output of the Countermeasures Task Force, the Vestibular Countermeasures Task Group, and the Behavior and Performance Working Group into a unified document. Available at the following Web address:

http://peer1.idi.usra.edu/peer_review/prog/countermeasures/countermeasures.html or (202) 358-4180.

30. **Workshop on Space Flight Validation of Radiation Risk**. January 24-26, 1996. Universities Space Research Association, 3600 Bay Area Boulevard, Houston, TX 77058

*Obtaining cited papers:

Many of the documents may be ordered through your library or through the National Technical Information Service (NTIS). Documents available through NTIS are accompanied by their NTIS order number and price. To order a document through NTIS, call 1-800-553-6847. If you are unable to locate a document through this means, please contact NASA Peer Review Services at 202-479-9030.

Flight Experiments in Space Life Sciences and Space Sciences NRA Requirements and Application Forms

This section contains the general instructions for notice of intent and proposal preparation and submission, including the specific forms required for proposal submission in response to agency solicitations for Flight Experiments in Space Life Sciences in 2001. Information presented in this Appendix is specific to this NRA and explains and enumerates Program requirements above and beyond those presented in Appendix C. In the event of any conflict between the instructions in Appendix B and Appendix C, Appendix B controls. For further clarification of each requirement, please refer to the appropriate section of Appendix C. The forms at the end of this section include the following:

Form A	Solicited Proposal Application
Form B	Proposal Abstract
Form C	Space Flight Experiment Information Summary
Form D	Biographical Sketch
Form E	Other Support
Form F	Detailed Budget, First Year
Form G	Detailed Budget, Entire Project Period
Form H	Checklist for Investigators

Instructions for Notice of Intent Submission

To facilitate proposal processing, potential Principal Investigators are requested to confirm plans to submit a proposal responding to this Announcement by sending a notice of intent to propose. As stated previously (see Research Announcement, Page 3) the notice of intent, which is not binding, should be submitted electronically by June 28, 2001. If you do not have access to electronic submission, you may submit a notice of intent by U.S. Postal Service or commercial delivery in the same manner as proposals.

As detailed on the electronic notice of intent submission form, the notice of intent should contain:

- A descriptive title of the research or technical proposal
- The names, addresses, and telephone numbers of a single Principal Investigator and all Co-Investigators
- The major participating institutions
- A brief summary describing the proposed research and clearly indicating the program element(s) defined in this Announcement that is/are most relevant to the proposal

• Up to six (6) key words that best describe the research area of the pending proposal

Instructions for Proposal Preparation

An original signed proposal, plus twenty-five (25) complete copies of the proposal and one 3.5-inch computer disk, should be mailed to the address indicated, and in the manner described, in the Research Announcement on Page 3 of this document. Proposal submission criteria and evaluation in the NRA supercede those in the companion documents.

<u>All</u> proposals must include each of the forms provided in this Appendix as part of the complete submission. The name of the Principal Investigator should appear in the upper right hand corner of each page of the proposal, except on the forms in this Appendix where special places are provided for this information. Note that the proposal <u>must</u> specify the period of performance for the work described; periods of performance may be for any duration up to three (3) years but should be suitable for the project proposed.

The proposal must include the following material, in this order:

(1) Cover Page: Solicited Proposal Application (Form A), including certification of compliance with U.S. code (if applicable). One signed original required.

For Item (7) on this form, <u>new</u> means that a proposal for this project has not been submitted to NASA from 1999 to 2001, <u>renewal</u> means that this proposal is for the continuation of a currently funded task beyond the term of the funded proposal, and <u>revised</u> means that this proposal represents a revision of a proposal submitted to NASA and reviewed from 1999 to 2001, but not funded. A proposal previously submitted but not funded should be termed revised even if the original Principal Investigator has changed for 2002. Renewal and revised applications should contain special material described in the Project Description section below. This form meets the requirements of the transmittal memo described in Appendix C, Section C (1).

(2) Proposal Abstract (Form B)

Includes a concise description of the objectives and methods of approach in less than 300 words. The information requested on this form is essential to the review of the proposal. It determines how the application will be evaluated and which program manager(s) will receive the final review materials.

(3) Proposal Title Page, with Notice on Restriction on Use and Disclosure of Proposal Information, if any (see Appendix C for details).

(4) Project Description

The length of the Project Description section of the proposal <u>cannot exceed 20 pages</u> using regular (12 point) type. Referenced figures must be included in the 20 pages of the Project Description. The Bibliography section is not considered part of the 20-

page project description. Proposals that exceed the 20-page limit for the project description (22 pages for revised proposals; see below) will not be reviewed. The proposal should contain sufficient detail to enable reviewers to make informed judgments about the overall merit of the proposed research and about the probability that the investigators will be able to accomplish their stated objectives with current resources and the resources requested. In addition, the proposal should clearly indicate the relationship between the proposed work and the research emphases defined in this Announcement. Reviewers are not required to consider information presented as appendices or to view and/or consider Web links in their evaluation of the proposal.

<u>Renewal applications</u> (for competing renewal of currently funded activity). Results and evidence of progress of the associated NASA supported research must be presented as part of the project description

Revised applications (revisions of 1998, 1999 or 2000 submissions) must be so designated on the proposal cover page and explained in the project description. This explanation should be presented in a separate section of **no more than two pages at the beginning of the project description** and is in addition to the 20 pages allowed for the project description. Related changes to the research plan should be highlighted in the body of the project description. Changes within the proposal may be highlighted by appropriate bracketing, indenting, or changing of typography. Clearly present any work done since the prior version was submitted. Revised applications that do not address the criticisms in the previous critique will be considered unresponsive and will be returned without review.

Space Flight Experiment Information Summary (Form C)

All applicants proposing space flight research <u>must</u> complete Form C. The information on this form is essential for the flight feasibility review of the proposed study. Before filling out this form, applicants must read the *Space Life Sciences and Space Sciences Flight Experiments Information Package* carefully and make certain that they understand the constraints associated with flight experiments. Keep in mind that the primary audience for this form is the international technical experts whose expertise may not include your specific area of research.

(5) Management Approach

Each proposal <u>must</u> specify a single Principal Investigator who is responsible for carrying out the proposed project and coordinating the work of other personnel involved in the project. In proposals that designate several senior professionals as key participants in the research project, the management approach section should define the roles and responsibilities of each participant and note the proportion of each individual's time to be devoted to the proposed research activity. The proposal must clearly and unambiguously state whether these key personnel have reviewed the proposal and endorsed their participation.

Letter of Assurance of Foreign Support

Proposals from non-U.S. entities that meet the criteria specified in Appendix A, Section VII must include a written endorsement from the respective agency or funding/sponsoring institution. In addition to sending the application to the designated address, one copy of the proposal, along with the letter of endorsement from the sponsoring non-U.S. government agency or funding sponsoring institution, must be forwarded to:

National Aeronautics and Space Administration Code I Office of External Relations 01-OBPR-03 Washington, DC 20546-0001 USA

(6) Biographical Sketch (Form C)

The biographical sketch should not exceed two pages. If the list of qualifications and publications exceeds two pages, select the most pertinent information (see Appendix C and Form C for details).

- (7) Other Support (Form D) (see Appendix C for details).
- (8) Facilities and Equipment (see Appendix C for details).
- (9) Special Matters (specific information on animal or human subjects protocol approval required, if applicable)

The Special Matters section must contain a statement from the investigator's institution that states that the proposed work will meet all Federal and local human subject requirements and animal care and use requirements, if applicable. Note that no animal subjects may be utilized unless specific information justifying and describing their use is included in the proposal. Policies regarding the protection of human research subjects in NASA-sponsored research are detailed in NASA Management Instruction (NMI) 7100.8B (Protection of Human Research Subjects), and animal care and use requirements are detailed in the NASA Code of Federal Regulations (CFR) 1232 (Care and Use of Animals in the Conduct of NASA Activities), both of which are available from the Office of Biological and Physical Research, Code UL, NASA Headquarters, Washington, DC 20546. Assurance of compliance with human subject or animal care provisions is required on Form A, to be submitted with each proposal. In addition, a letter signed by the chairperson of the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC), or both, as appropriate, regarding approval of the experimental protocol, should be included with each copy of the proposal. If IRB or IACUC review is

unavoidably delayed beyond the submission of the application, enter "Pending" on Line 9b or 10a of Form A, and be advised that the certification must be received within 60 days after the due date for which the application is submitted. If certification is not received within 60 days after the application due date, the application will be considered incomplete and will not be reviewed. NASA shall require current IRB or IACUC certification prior to each year's award. All U.S., non-NASA proposals providing IACUC approval must also contain the institution's Public Health Assurance number.

(10) Detailed Budget, 12 Month (Form E)

(11) Detailed Budget, Entire Project Period (Form F)

NASA is expected to be operating on the basis of full cost accounting as soon as possible, including all Civil Service salaries with overhead. In the interim period, proposals should use the accounting method authorized at their institutions at the time proposals are due and for the entire proposed period of performance. Funds to support the Resident Research Assistant (RRA) Postdoctoral Program costs (e.g., stipend, travel, computer time, supplies, etc.) are to be budgeted within the NASA intramural Principal Investigator budget.

The process of implementing a flight experiment will require the Principal Investigator to visit NASA field centers for such activities and training, informed consent briefings, baseline data collection, post flight sample processing, etc. The proposal budget should include appropriate travel funds for such visits as well as for the presentation of findings at professional society meetings.

(12) Supporting Budgetary Information

This section must include information that supports the costs submitted in Forms E and F. In this solicitation, the terms "cost" and "budget" are used synonymously. Sufficient proposal cost detail and supporting information are required; funding amounts proposed with no explanation (e.g., Equipment: \$1,000, or Labor: \$6,000) may cause delays in evaluation and award. Generally, costs will be evaluated as to realism, reasonableness, allowability, and allocation. The budgetary forms define the desired detail, but each category should be explained in this section. Offerors should exercise prudent judgment in determining what to include in the proposal, as the amount of detail necessarily varies with the complexity of the proposal.

The following examples indicate the suggested method of preparing a cost breakdown:

Direct Labor

Labor costs should be segregated by titles or disciplines with estimated hours and rates for each. Estimates should include a basis of estimate, such as currently paid

rates or outstanding offers to prospective employees. This format allows the Government to assess cost reasonableness by various means including comparison to similar skills at other organizations.

Other Direct Costs

Please detail, explain, and substantiate other significant cost categories as described below:

- <u>Subcontracts</u>: Describe the work to be contracted, estimated amount, recipient (if known), and the reason for subcontracting.
- <u>Consultants</u>: Identify consultants to be used, why they are necessary, the time they will spend on the project, and the rates of pay.
- Equipment: List separately. Explain the need for items costing more than \$5,000. Describe basis for estimated cost. General purpose equipment is not allowable as a direct cost unless specifically approved by the NASA Grant Officer. Any equipment purchase requested as a direct charge must include the equipment description, how it will be used in the conduct of the basic research proposed, and why it cannot be purchased with indirect funds.
- <u>Supplies</u>: Provide general categories of needed supplies, the method of acquisition, and estimated cost.
- <u>Travel</u>: Describe the purpose of the proposed travel in relation to the grant and provide the basis of estimate, including information on destination and number of travelers where known.
- Other: Enter the total of direct costs not covered by the categories listed above. Attach an itemized list explaining the need for each item and the basis for the estimate.

Indirect Costs

Indirect costs should be explained to an extent that will allow the Government to understand the basis for the estimate. Examples of prior year historical rates, current variances from those rates, or an explanation of other basis of estimates should be included. Where costs are based on allocation percentages or dollar rates, an explanation of rate and application base relationships should be given. For example, the base to which the General and Administrative (G&A) rate is applied could be explained as: application base equals total costs before G&A less subcontracts.

All awards made as a result of this NRA may be funded as grants or contracts. However, while proposals submitted by "for profit" organizations are allowed, they cannot include a "fee."

- (13) Checklist for Investigators (Form G)
- (14) Appendices, if any (reviewers are not required to consider information presented in appendices)

(15) Computer diskette (3.5 inch, PC format) containing an electronic copy of the principal investigator's name, address, telephone and fax numbers, e-mail address, and the complete project title and abstract as provided on Form B.

CERTIFICATION REGARDING DEBARMENT, SUSPENSION, AND OTHER RESPONSIBILITY MATTERS

PRIMARY COVERED TRANSACTIONS

This certification is required by the regulations implementing Executive Order 12549, Debarment and Suspension, 14 CFR Part 1269.

A. The applicant certifies that it and its principals:

- (a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal department or agency;
- (b) Have not within a three-year period preceding this application been convicted or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or Local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;
- (c) Are not presently indicted for or otherwise criminally or civilly charged by a government entity (Federal, State, or Local) with commission of any of the offenses enumerated in paragraph A.(b) of this certification; and
- (d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State, or Local) terminated for cause or default; and
- B. Where the applicant is unable to certify to any of the statements in this certification, he or she shall attach an explanation to this application.
- C. Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion Lowered Tier Covered Transactions (Subgrants or Subcontracts)
 - a) The prospective lower tier participant certifies, by submission of this proposal, that neither it nor its principles is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department of agency.
- Where the prospective lower tier participant is unable to certify to any of the statements in this certification, such prospective participant shall attach an explanation to this proposal.

This page has been included for your information. Do not submit this page with your application. Item 21 of Form A satisfies the requirement of compliance with the provisions, rules, and stipulations described on this page.

CERTIFICATION REGARDING LOBBYING

As required by S 1352 Title 31 of the U.S. Code for persons entering into a grant or cooperative agreement over \$100,000, the applicant certifies that:

- (a) No Federal appropriated funds have been paid or will be paid by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, in connection with making of any Federal grant, the entering into of any cooperative, and the extension, continuation, renewal, amendment, or modification of any Federal grant or cooperative agreement;
- (b) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting an officer or employee of any agency, Member of Congress, an or an employee of a Member of Congress in connection with this Federal grant or cooperative agreement, the undersigned shall complete Standard Form LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- (c) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subgrants, contracts under grants and cooperative agreements, and subcontracts), and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by S1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

This page has been included for your information. Do not submit this page with your application. Item 21 of Form A satisfies the requirement of compliance with the provisions, rules, and stipulations described on this page.

CERTIFICATION OF COMPLIANCE WITH THE NASA REGULATIONS PURSUANT TO

NONDISCRIMINATION IN FEDERALLY ASSISTED PROGRAMS

The (Institution, corporation, firm, or other organization on whose behalf this assurance is signed, hereinafter called "Applicant") hereby agrees that it will comply with Title VI of the Civil Rights Act of 1964 (P.L. 88-352), Title IX of the Education Amendments of 1962 (20 U.S. 1680 et seq.), Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S. 794), and the Age Discrimination Act of 1975 (42 U.S. 16101 et seq.), and all requirements imposed by or pursuant to the Regulation of the National Aeronautics and Space Administration (14 CFR Part 1250) (hereinafter called "NASA") issued pursuant to these laws, to the end that in accordance with these laws and regulations, no person in the United States shall, on the basis of race, color, national origin, sex, handicapped condition, or age be excluded from participating in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity for which the Applicant receives federal financial assistance from NASA; and hereby give assurance that it will immediately take any measure necessary to effectuate this agreement.

If any real property or structure thereon is provided or improved with the aid of federal financial assistance extended to the Applicant by NASA, this assurance shall obligate the Applicant, or in the case of any transfer of such property, any transferee, for the period during which the real property or structure is used for a purpose for which the federal financial assistance is extended or for another purpose involving the provision of similar services or benefits. If any personal property is so provided, this assurance shall obligate the Applicant for the period during which the federal financial assistance is extended to it by NASA.

This assurance is given in consideration of and for the purpose of obtaining any and all federal grants, loans, contracts, property, discounts, or other federal financial assistance extended after the date hereof to the Applicant by NASA, including installment payments after such date on account of applications for federal financial assistance which were approved before such date. The Applicant recognized and agrees that such federal financial assistance will be extended in reliance on the representations and agreements made in this assurance, and the United States shall have the right to seek judicial enforcement of this assurance. His assurance is binding on the Applicant, its successors, transferees, and assignees, and the person or persons whose signatures appear below are authorized to sign on behalf of the Applicant.

This page has been included for your information. Do not submit this page with your application. Item 21 of Form A satisfies the requirement of compliance with the provisions, rules, and stipulations described on this page.

The Required Application Forms must be downloaded separately from

http://peer1.idi.usra.edu/peer_review/nra/01_OBPR_03.html

Instructions for Responding to NASA Research Announcements

(January 2000)

(a) General.

- (1) Proposals received in response to a NASA Research Announcement (NRA) will be used only for evaluation purposes. NASA does not allow a proposal, the contents of which are not available without restriction from another source, or any unique ideas submitted in response to an NRA to be used as the basis of a solicitation or in negotiation with other organizations, nor is a pre-award synopsis published for individual proposals.
- (2) A solicited proposal that results in a NASA award becomes part of the record of that transaction and may be available to the public on specific request; however, information or material that NASA and the awardee mutually agree to be of a privileged nature will be held in confidence to the extent permitted by law, including the Freedom of Information Act.
- (3) NRAs contain programmatic information and certain requirements which apply only to proposals prepared in response to that particular announcement. These instructions contain the general proposal preparation information which applies to responses to all NRAs.
- (4) A contract, grant, cooperative agreement, or other agreement may be used to accomplish an effort funded in response to an NRA. NASA will determine the appropriate instrument. Contracts resulting from NRAs are subject to the Federal Acquisition Regulation and the NASA FAR Supplement. Any resultant grants or cooperative agreements will be awarded and administered in accordance with the NASA Grant and Cooperative Agreement Handbook (NPG 5800.1).
- (5) NASA does not have mandatory forms or formats for responses to NRAs; however, it is requested that proposals conform to the guidelines in these instructions. NASA may accept proposals without discussion; hence, proposals should initially be as complete as possible and be submitted on the investigators' most favorable terms.
- (6) To be considered for award, a submission must, at a minimum, present a specific project within the areas delineated by the NRA; contain sufficient technical and cost information to permit a meaningful evaluation; be signed by an official authorized to

legally bind the submitting organization; not merely offer to perform standard services or to just provide computer facilities or services; and not significantly duplicate a more specific current or pending NASA solicitation.

- (b) NRA-Specific Items. Several proposal submission items appear in the NRA itself: the unique NRA identifier; when to submit proposals; where to send proposals; number of copies required; and sources for more information. Items included in these instructions may be supplemented by the NRA.
- (c) The following information is needed to permit consideration in an objective manner. NRAs will generally specify topics for which additional information or greater detail is desirable. Each proposal copy shall contain all submitted material, including a copy of the transmittal letter if it contains substantive information.
 - (1) Transmittal Letter or Prefatory Material.
 - (i) The legal name and address of the organization and specific division or campus identification if part of a larger organization;
 - (ii) A brief, scientifically valid project title intelligible to a scientifically literate reader and suitable for use in the public press;
 - (iii) Type of organization: e.g., profit, nonprofit, educational, small business, minority, women-owned, etc.;
 - (iv) Name and telephone number of the principal investigator and business personnel who may be contacted during evaluation or negotiation;
 - (v) Identification of other organizations that are currently evaluating a proposal for the same efforts:
 - (vi) Identification of the NRA, by number and title, to which the proposal is responding;
 - (vii) Dollar amount requested, desired starting date, and duration of project;
 - (viii) Date of submission; and
 - (ix) Signature of a responsible official or authorized representative of the organization, or any other person authorized to legally bind the organization (unless the signature appears on the proposal itself).
 - (2) Restriction on Use and Disclosure of Proposal Information. Information contained in proposals is used for evaluation purposes only. Offerors or quoters should, in order to maximize protection of trade secrets or other information that is confidential or privileged, place the following notice on the title page of the proposal and specify the information

subject to the notice by inserting an appropriate identification in the notice. In any event, information contained in proposals will be protected to the extent permitted by law, but NASA assumes no liability for use and disclosure of information not made subject to the notice.

Notice

Restriction on Use and Disclosure of Proposal Information

The information (data) contained in [insert page numbers or other identification] of this proposal constitutes a trade secret and/or information that is commercial or financial and confidential or privileged. It is furnished to the Government in confidence with the understanding that it will not, without permission of the offeror, be used or disclosed other than for evaluation purposes; provided, however, that in the event a contract (or other agreement) is awarded on the basis of this proposal the Government shall have the right to use and disclose this information (data) to the extent provided in the contract (or other agreement). This restriction does not limit the Government's right to use or disclose this information (data) if obtained from another source without restriction.

- (3) Abstract. Include a concise (200-300 word if not otherwise specified in the NRA) abstract describing the objective and the method of approach.
- (4) Project Description.
 - (i) The main body of the proposal shall be a detailed statement of the work to be undertaken and should include objectives and expected significance; relation to the present state of knowledge; and relation to previous work done on the project and to related work in progress elsewhere. The statement should outline the plan of work, including the broad design of experiments to be undertaken and a description of experimental methods and procedures. The project description should address the evaluation factors in these instructions and any specific factors in the NRA. Any substantial collaboration with individuals not referred to in the budget or use of consultants should be described. Subcontracting significant portions of a research project is discouraged.
 - (ii) When it is expected that the effort will require more than one year, the proposal should cover the complete project to the extent that it can be reasonably anticipated. Principal emphasis should be on the first year of work, and the description should distinguish clearly between the first year's work and work planned for subsequent years.
- (5) Management Approach. For large or complex efforts involving interactions among numerous individuals or other organizations, plans for distribution of responsibilities and arrangements for ensuring a coordinated effort should be described.

(6) Personnel. The principal investigator is responsible for supervision of the work and participates in the conduct of the research regardless of whether or not compensated under the award. A short biographical sketch of the principal investigator, a list of principal publications and any exceptional qualifications should be included. Omit social security number and other personal items that do not merit consideration in evaluation of the proposal. Give similar biographical information on other senior professional personnel who will be directly associated with the project. Give the names and titles of any other scientists and technical personnel associated substantially with the project in an advisory capacity. Universities should list the approximate number of students or other assistants, together with information as to their level of academic attainment. Any special industry-university cooperative arrangements should be described.

(7) Facilities and Equipment.

- (i) Describe available facilities and major items of equipment especially adapted or suited to the proposed project, and any additional major equipment that will be required. Identify any Government-owned facilities, industrial plant equipment, or special tooling that are proposed for use. Include evidence of its availability and the cognizant Government points of contact.
- (ii) Before requesting a major item of capital equipment, the investigator should determine if sharing or loan of equipment already within the organization is a feasible alternative. Where such arrangements cannot be made, the proposal should so state. The need for items that typically can be used for research and non-research purposes should be explained.

(8) Proposed Costs (U.S. Proposals Only).

- (i) Proposals should contain cost and technical parts in one volume: do not use separate "confidential" salary pages. As applicable, include separate cost estimates for salaries and wages; fringe benefits; equipment; expendable materials and supplies; services; domestic and foreign travel; ADP expenses; publication or page charges; consultants; subcontracts; other miscellaneous identifiable direct costs; and indirect costs. List salaries and wages in appropriate organizational categories (e.g., principal investigator, other scientific and engineering professionals, graduate students, research assistants, and technicians and other non-professional personnel). Estimate all staffing data in terms of staff-months or fractions of full-time.
- (ii) Explanatory notes should accompany the cost proposal to provide identification and estimated cost of major capital equipment items to be acquired; purpose and estimated number and lengths of trips planned; basis for indirect cost computation (including date of most recent negotiation and cognizant agency); and clarification of other items in the cost proposal that are not self-evident. List estimated expenses as yearly requirements by major work phases.

- (iii) Allowable costs are governed by FAR Part 31 and the NASA FAR Supplement Part 1831 (and OMB Circulars A-21 for educational institutions and A-122 for nonprofit organizations).
- (iv) Use of NASA funds--NASA funding may not be used for foreign research efforts at any level, whether as a collaborator or a subcontract. The direct purchase of supplies and/or services, which do not constitute research, from non-U.S. sources by U.S. award recipients is permitted. Additionally, in accordance with the National Space Transportation Policy, use of a non-U.S. manufactured launch vehicle is permitted only on a no-exchange-of-funds basis.
- (9) Security. Proposals should not contain security classified material. If the research requires access to or may generate security classified information, the submitter will be required to comply with Government security regulations.
- (10) Current Support. For other current projects being conducted by the principal investigator, provide title of project, sponsoring agency, and ending date.

(11) Special Matters.

- (i) Include any required statements of environmental impact of the research, human subject or animal care provisions, conflict of interest, or on such other topics as may be required by the nature of the effort and current statutes, executive orders, or other current Government-wide guidelines.
- (ii) Investigators should include a brief description of the organization, its facilities, and previous work experience in the field of the proposal. Identify the cognizant Government audit agency, inspection agency, and administrative contracting officer, when applicable.

(d) Renewal Proposals.

- (1) Renewal proposals for existing awards will be considered in the same manner as proposals for new endeavors. A renewal proposal should not repeat all of the information that was in the original proposal. The renewal proposal should refer to its predecessor, update the parts that are no longer current, and indicate what elements of the research are expected to be covered during the period for which support is desired. A description of any significant findings since the most recent progress report should be included. The renewal proposal should treat, in reasonable detail, the plans for the next period, contain a cost estimate, and otherwise adhere to these instructions.
- (2) NASA may renew an effort either through amendment of an existing contract or by a new award.
- (e) Length. Unless otherwise specified in the NRA, effort should be made to keep proposals as brief as possible, concentrating on substantive material. Few proposals need exceed 15-20

pages. Necessary detailed information, such as reprints, should be included as attachments. A complete set of attachments is necessary for each copy of the proposal. As proposals are not returned, avoid use of "one-of-a-kind" attachments.

(f) Joint Proposals.

- (1) Where multiple organizations are involved, the proposal may be submitted by only one of them. It should clearly describe the role to be played by the other organizations and indicate the legal and managerial arrangements contemplated. In other instances, simultaneous submission of related proposals from each organization might be appropriate, in which case parallel awards would be made.
- (2) Where a project of a cooperative nature with NASA is contemplated, describe the contributions expected from any participating NASA investigator and agency facilities or equipment which may be required. The proposal must be confined only to that which the proposing organization can commit itself. "Joint" proposals which specify the internal arrangements NASA will actually make are not acceptable as a means of establishing an agency commitment.
- (g) Late Proposals. Proposals or proposal modifications received after the latest date specified for receipt may be considered if a significant reduction in cost to the Government is probable or if there are significant technical advantages, as compared with proposals previously received.
- (h) Withdrawal. Proposals may be withdrawn by the investigator at any time before award. Offerors are requested to notify NASA if the proposal is funded by another organization or of other changed circumstances which dictate termination of evaluation.

(i) Evaluation Factors.

- (1) Unless otherwise specified in the NRA, the principal elements (of approximately equal weight) considered in evaluating a proposal are its relevance to NASA's objectives, intrinsic merit, and cost.
- (2) Evaluation of a proposal's relevance to NASA's objectives includes the consideration of the potential contribution of the effort to NASA's mission.
- (3) Evaluation of its intrinsic merit includes the consideration of the following factors of equal importance:
 - (i) Overall scientific or technical merit of the proposal or unique and innovative methods, approaches, or concepts demonstrated by the proposal.
 - (ii) Offeror's capabilities, related experience, facilities, techniques, or unique combinations of these, which are integral factors for achieving the proposal objectives.
 - (iii) The qualifications, capabilities, and experience of the proposed principal

investigator, team leader, or key personnel critical in achieving the proposal objectives.

- (iv) Overall standing among similar proposals and/or evaluation against the state-of-the-art.
- (4) Evaluation of the cost of a proposed effort may include the realism and reasonableness of the proposed cost and available funds.
- (j) Evaluation Techniques. Selection decisions will be made following peer and/or scientific review of the proposals. Several evaluation techniques are regularly used within NASA. In all cases, proposals are subject to scientific review by discipline specialists in the area of the proposal. Some proposals are reviewed entirely in-house, others are evaluated by a combination of in-house and selected external reviewers, while yet others are subject to the full external peer review technique (with due regard for conflict-of-interest and protection of proposal information), such as by mail or through assembled panels. The final decisions are made by a NASA selecting official. A proposal that is scientifically and programmatically meritorious, but not selected for award during its initial review, may be included in subsequent reviews unless the investigator requests otherwise.

(k) Selection for Award.

- (1) When a proposal is not selected for award, the investigator will be notified. NASA will explain generally why the proposal was not selected. Investigators desiring additional information may contact the selecting official, who will arrange a debriefing.
- (2) When a proposal is selected for award, negotiation and award will be handled by the procurement office in the funding installation. The proposal is used as the basis for negotiation. The contracting officer may request certain business data and may forward a model award instrument and other information pertinent to negotiation.
- (l) Additional Guidelines Applicable to Foreign Proposals and Proposals Including Foreign Participation.
 - (1) NASA welcomes proposals from outside the U.S. However, foreign entities are generally not eligible for funding from NASA. Therefore, unless otherwise noted in the NRA, proposals from foreign entities should not include a cost plan unless the proposal involves collaboration with a U.S. institution, in which case a cost plan for only the participation of the U.S. entity must be included. Proposals from foreign entities and proposals from U.S. entities that include foreign participation must be endorsed by the respective government agency or funding/sponsoring institution in the country from which the foreign entity is proposing. Such endorsement should indicate that the proposal merits careful consideration by NASA, and if the proposal is selected, sufficient funds will be made available to undertake the activity as proposed.

- (2) All foreign proposals must be typewritten in English and comply with all other submission requirements stated in the NRA. All foreign proposals will undergo the same evaluation and selection process as those originating in the U.S. All proposals must be received before the established closing date. Those received after the closing date will be treated in accordance with paragraph (g) of this provision. Sponsoring foreign government agencies or funding institutions may, in exceptional situations, forward a proposal without endorsement if endorsement is not possible before the announced closing date. In such cases, the NASA sponsoring office should be advised when a decision on endorsement can be expected.
- (3) Successful and unsuccessful foreign entities will be contacted directly by the NASA sponsoring office. Copies of these letters will be sent to the foreign sponsor. Should a foreign proposal or a U.S. proposal with foreign participation be selected, NASA's Office of External Relations will arrange with the foreign sponsor for the proposed participation on a no-exchange-of-funds basis, in which NASA and the non-U.S. sponsoring agency or funding institution will each bear the cost of discharging their respective responsibilities.
- (4) Depending on the nature and extent of the proposed cooperation, these arrangements may entail:
 - (i) An exchange of letters between NASA and the foreign sponsor; or
 - (ii) A formal Agency-to-Agency Memorandum of Understanding (MOU).
- (m) Cancellation of NRA. NASA reserves the right to make no awards under this NRA and to cancel this NRA. NASA assumes no liability for canceling the NRA or for anyone's failure to receive actual notice of cancellation.

Critical Path Roadmap/Critical Questions Related to Research Thrusts

NASA has developed a Critical Path Research Plan (http://criticalpath.jsc.nasa.gov/) to guide its bioastronautics research in systematically reducing or eliminating the risks to astronaut health, safety, and performance during and after space flight. Of the 55 risks identified in the Critical Path Roadmap (CPR), this 2001 Flight Research Solicitation focuses on the following 11 risks (#9, 10, 11, 28, 29, 30, 31, 34, 48, 49, 54) associated with altered musculoskeletal function, and three risks associated with human behavior and performance (18, 20, 21). The Critical Path poses 250 unique critical questions (CQ) detailing the unknowns thought to be required to mitigate the 55 critical risks. Proposals submitted in response to this solicitation MUST seek to answer one or more of the following critical questions related to musculoskeletal function or behavior and performance:

Bone Loss

Risk No. 9

Acceleration of Age-Related Osteoporosis: Failure to recover bone lost during mission coupled with age-related bone loss can lead to osteoporotic fractures at a younger age.

- **2.03** Will bone mass loss continue unabated for missions greater than six months in duration, or will it eventually plateau at some time consistent with absolute bone mineral density? Is this "minimum BMD" site-specific or consistent over numerous skeletal sites?
- **2.09** What are the most important predictors for bone loss during prolonged exposure to hypogravity, especially with reference to ethnicity, gender, age, baseline BMD, and bone morphometry (e.g., femoral neck length)?
- **2.19** Is bone loss reversible and within what time frame: Can geometry and architecture return to baseline as well as BMD?
- **2.20** What is the most optimal rehabilitation regimen upon return to normal gravity to maximize return to baseline BMD and bone morphometry, especially given that muscle strength will recover more quickly than bone strength?
- **2.25** Can the pattern of reversibility be correlated with serum or urine biomarkers of bone turnover?

(Bone Loss, Risk 9 continued)

2.26 How does treatment initiation in returning crew with bone loss diminish the risk of postflight fracture by facilitating more rapid return to preflight bone status?

Risk No. 10

Fracture and Impaired Fracture Healing: *Increased risk of fracture (traumatic, stress, avulsion)* upon return to activity in 1g due to hypogravity-induced bone loss.

- **2.03** Will bone mass loss continue unabated for missions greater than six months in duration, or will it eventually plateau at some time consistent with absolute bone mineral density? Is this "minimum BMD" site-specific or consistent over numerous skeletal sites?
- **2.04** What localized bone changes at tendon sites would contribute to increased risk of avulsion fractures (i.e., how much disparity between bone & muscle strength can be incurred without increased risk of avulsion fracture?
- **2.06** What pharmacological agents will most effectively minimize the decrease in bone mass with hypogravity? Are anabolic as well as anti-resorptive agents required?
- **2.07** What are the specifics of the optimal exercise regimen to be followed during exposure to hypogravity to minimize decreases in bone mass with regard to workout duration, intensity, and frequency? Is impact loading an essential element?
- **2.08** Is there an optimal combination of exercise (an anabolic stimulus) and a pharmacological countermeasure (anti-resorptive) to minimize decrements in bone mass in hypogravity?
- **2.09** What are the most important predictors for bone loss during prolonged exposure to hypogravity, especially with reference to ethnicity, gender, age, baseline BMD, and bone morphometry (e.g., femoral neck length)?
- **2.10** Does hypogravity exposure change the nutritional requirements for optimal bone health (e.g., does calcium absorption decrease)?
- **2.11** Does prolonged exposure to hypogravity lead to non-union of healing fractures? What evidence supports the alteration in vertebral morphometry during and after extended spaceflight?
- **2.13** Does hypogravity affect size, viability or differentiation of precursor bone cell populations?

(Bone Loss, Risk 10 continued)

- **2.14** What practical diagnostic tools can be utilized during multi-year missions to monitor and quantify changes in bone mass and strength (e.g., biochemical markers, DEXA, ultrasound)?
- **2.15** Are there important other mechanisms for bone loss with hypogravity that are critical to developing effective countermeasures (e.g., fluid shifts with altered hydrostatic pressure, changes in blood flow, immune system alterations)?
- **2.26** How does treatment initiation in returning crew with bone loss diminish the risk of postflight fracture by facilitating more rapid return to preflight bone status?

Risk No. 11

Injury to Soft Connective Tissue, Joint Cartilage, Intervertebral Disc Rupture with or without Neurological Complications: Fascia, tendon and ligament overuse or traumatic injury, joint dysfunction upon return to normal/partial gravity. Hypogravity changes to intervertebral discs may increase risk of rupture, with attendant back pain and possible neurological complications.

Critical Questions:

- **2.17** What is the incidence of soft connective tissue injury and pain during recovery after prolonged hypogravity or bed rest? Use pre- and postflight analyses of MRI scan of spine and extremities and postflight follow-up studies over six months to one year.
- **2.18** What countermeasures can reduce the incidence of soft connective tissue injury and pain during recovery after prolonged hypogravity or bed rest?

Muscle Alterations and Atrophy

Risk No. 28

Loss of Skeletal Muscle Mass, Strength, and/or Endurance: *The inability to perform emergency egress, landing and in partial gravity due to significant losses of muscle mass, strength and/or endurance. Such reduction would affect the ability to perform emergency egress, movements required for landing in partial gravity (fine motor control) and piloting prior to landing.*

- **8.01** What are the appropriate prescription modalities and the compliance factors needed to minimize losses in muscle mass, strength and endurance, and facilitate rehabilitation?
- **8.02** To what extent should hormonal/pharmacological supplements be used as a countermeasure if exercise regimens are ineffective in maintaining homeostasis?

(Muscle Alterations and Atrophy, Risk 28 continued)

- **8.03** What is the role of, and what is necessary in order to establish the hormonal profile of astronauts during long duration spaceflight?
- **8.08** What are the appropriate exercise modalities and prescriptions needed to optimize skeletal muscle performance?

Risk No. 29

Inability to Adequately Perform Tasks Due to Motor Performance, Muscle Endurance, and Disruptions in Structural and Functional Properties of Soft and Hard Connective Tissues of the Axial Skeleton: *Inability to perform a variety of tasks associated with microgravity EVA, IVA and daily activities due to motor performance, muscle endurance and disruptions in the structural and functional properties (including phenotype) of the soft and hard connective tissues of the axial skeleton (i.e. intervertebral disk, lower back syndrome).*

Critical Questions:

- **8.01** What are the appropriate prescription modalities and the compliance factors needed to minimize losses in muscle mass, strength and endurance, and facilitate rehabilitation?
- **8.02** To what extent should hormonal/pharmacological supplements be used as a countermeasure if exercise regimens are ineffective in maintaining homeostasis?
- **8.03** What is the role of, and what is necessary in order to establish the hormonal profile of astronauts during long duration spaceflight?
- **8.08** What are the appropriate exercise modalities and prescriptions needed to optimize skeletal muscle performance?

Risk No. 30

Inability to Sustain Muscle Performance Levels to Meet Demands of Performing Activities of Varying Intensities: The inability to sustain muscle performance levels to meet the demands of performing mission-specific activities of varying intensities. Included in this risk is that deficits will exist in the maintenance of gait and posture that are required to complete these activities. An additional concern is that sufficient nutritional provisions may not be available to provide the necessary substrate energy to complete these tasks.

- **8.04** What effect does long-term spaceflight/operational countermeasure have on nitrogen balance (i.e., anabolic/catabolic control of protein expression)?
- **8.05** What are the effects of long-term spaceflight on the metabolism of carbohydrates and fats, and what is their influence on sustained aerobic work and performance?

(Muscle Alterations and Atrophy continued)

Risk No. 31

Propensity to Develop Muscle Injury, Connective Tissue Dysfunction, and Bone Fractures Due to Deficiencies in Motor Skill, Muscle Strength and Muscular Fatigue

Critical Questions:

- **8.06** Do the deficits in skeletal muscle associated with long duration spaceflight affect the structural/functional properties of the sensory system and motor nerves? Describe the changes in muscle tendon interface.
- **8.07** Do structural and functional deficits in skeletal muscle system associated with long duration spaceflight impact: neurovestibular homeostasis; cardiovascular deconditioning; deficits in bone (regional & general); the muscle and tendon interface, and feedback from skeletal muscle to CNS (hypothalamus, hypophysis)?

Neurovestibular Adaptation

Risk No. 34

Impaired Neuromuscular Coordination and/or Strength (Gait ataxia, postural instability): Impaired neuromuscular strength upon return to positive G leading to increased occurrence of falls and fractures during emergency egress and escape.

Critical Questions:

- **9.22** What is the relative contribution of neurovestibular adaptation, neuromuscular deconditioning, and orthostatic intolerance to postflight neuromuscular coordination, ataxia and locomotion difficulties?
- **9.24** Can preflight or inflight training, or sensory aids and prostheses improve postlanding postural and locomotor control?

Clinical Capabilities

Risk No. 48

Difficulty of Rehabilitation Following Landing: *Post-landing alterations in cardiovascular, musculoskeletal and neurosensory systems resulting in severe performance decrements, injuries, and long-term sequelae.*

Critical Questions:

11.37 What are the essential technologies, resources, protocols, skills and training necessary for post-landing performance, recovery and rehabilitation (including psychological, cardiovascular, neurosensory, musculoskeletal, and nutritional)?

(Clinical Capabilities, Risk 48 continued)

- 11.38 What pre-landing and pre-egress performance and health parameters should be monitored to assure adequate cardiovascular tone, neurological function, skeletal integrity, muscular strength, and endurance?
- 11.39 What are the issues related to and resources required for long-term rehabilitation and recovery from long duration spaceflight?

Multisystem (Cross Risk) Alterations

Risk No. 49

Postlanding Alterations in Various Systems Resulting in Performance Decrements and Injuries: As the human adapts to the changing conditions of microgravity, alterations in any one physiological system may affect the function of other systems. The primary issue is to understand how post-landing alterations in multiple systems may result in performance decrements or increased injury, and to identify the preventative or rehabilitation strategies for facilitating post-flight recovery of function and performance.

Critical Question:

3.23 What rehabilitative measures should be applied after mission completion?

Food and Nutrition

Risk No. 54

Difficulty of Rehabilitation Following Landing Due to Nutritional Deficiencies: *Excessive time required to return to health and full duty status*.

- **5.15** What are the decrements in nutritional status due to long-term space flight?
- **5.16** What monitoring (biochemical, anthropometric, clinical assessments) during rehabilitation is required?
- **5.17** What level of dietary counseling is needed for crewmembers during rehabilitation?
- **5.18** Are there inflight countermeasures that affect nutritional status (promote or cause) decrements?

Human Behavior and Performance

Risk No. 18

Human Performance Failure due to Poor Psychosocial Adaptation

Critical Questions:

- **6.01** What are the fundamental behavioral and social stressors during long-duration missions that will most likely affect crew performance, both individual and team?
- **6.03** What behaviors, experiences, personality traits, and leadership styles in crewmembers most contribute to optimal performance? How are these related to team performance?
- **6.04** What crewmember behaviors, experiences, personality traits, and leadership styles that optimize performance can be identified during the selection process and be used to select and assemble the best teams for long duration missions?

Risk No. 20

Human Performance Failure because of Human System Interface Problems and Ineffective Habitat and Equipment Design, Workload, and or Inflight Information and Training Systems

- **6.11** What methods of assessing human performance capabilities will be most effective and usable during a Mars mission?
- **6.12** What factors in systems and habitat design will best enhance the crew's ability to live and work in the space environment? How are these factors different from shorter duration missions?
- **6.22** What theoretical, analytical and computational models of human performance best predict changes in human performance capabilities and characteristics in the context of a Mars mission, and enable designing and evaluating systems, procedures, and interface designs to mitigate negative changes in performance capabilities?

Risk No. 21

Human Performance Failure due to Neurobehavioral Dysfunction

Critical Questions:

6.15 What are the acute and long-term effects of exposure to the space environment on the human cognition and performance capabilities, including processes of sensation and perception, learning, vigilance, cognition, problem solving, decision making, and motor skills?

(Human Behavior and Performance, Risk 21 continued)

- **6.16** What are the acute and long-term effects of exposure to the space environment (microgravity, isolation, stress) on the nervous system (at the cellular, molecular, or organismic levels) and on related neurobehavioral mechanisms, including neurobiology related to behavior and mood regulation?
- **6.19** What are the acute and long-term effects of exposure to the space environment on human emotion and psychological responses, including emotional reactivity, stress responses, long-term modulation of mood, and vulnerability to affective disorders?
- **6.20** What are the best methods of inflight monitoring for neurobehavioral dysfunction, including cognitive and performance dysfunction, emotional and stress-related dysfunction, neuropsychiatric dysfunction, and social psychological dysfunction?